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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/541,873	04/03/2000	James P. Pearson	UIZ-003DVCN	4136

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/541,873	PEARSON ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Preliminary Amendments* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-79* is/are pending in the application.

4a) Of the above claim(s) *46-53 and 77-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44,45 and 54-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *44-79* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,9,10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Please note that the Patent Examiner of your application in the PTO has changed. All communications should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (703)308-4244.

2. Applicants' Preliminary Amendment, paper#5, is acknowledged. Claims 2-43 have been canceled.

3. Applicants' Amendment, received 11July2001, paper#8, is acknowledged. Claim 1 has been canceled. Claims 44-53 have been added.

4. Applicants' Amendment, received 18September2002, paper#15, is acknowledged. Claim 44 has been amended. New claims 54-79 have been added.

5. Claims 44-79 are pending.

Restriction

6. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 44, 45, and 54-76, drawn to method of identifying compounds which alter autoinducer activity , classified in class 435, subclass 4.

II. Claims 46 and 47, drawn to culture medium, classified in class 435, subclass 243.

III. Claims 48-53, drawn to method of regulating gene expression, classified in class 536, subclass 23.7.

IV. Claims 77-79, drawn to inhibitor compounds, classified in class 536, subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the medium of Invention II can be utilized for growing bacteria in general.

Inventions I and III are drawn to patentably distinct methods utilizing different reagents and having different outcomes. Invention I is a method to identify compounds which alter autoinducer activity. Invention III is a method of regulating gene expression.

Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the compounds of Invention IV can be utilized to produce antibodies which interfere with inhibition of *P. aeruginosa* autoinducers.

Invention II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the medium of Invention II can be utilized for growing bacteria in general.

Invention II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP 806.05(h)). In the instant case, the medium of Invention II can be utilized for growing bacteria in general.

Invention III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the compounds of Invention IV can be utilized to produce antibodies which interfere with inhibition of *P. aeruginosa* autoinducers.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and because while the searches may overlap, the searches are not coextensive, restriction for examination purposes as indicated is proper.

Provisional Election

7. During a telephone conversation with Peter Lauro, Reg. No. 32,360, on 4June2003 and 5June2003, a provisional election was made without traverse to prosecute the invention of Invention I, claims 44, 45, and 54-76. Affirmation of this election must be made by applicant in replying to this Office action. Claims 46-53 and 77-79 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Claims 44, 45, and 54-76 are under consideration.

Specification

9. The disclosure is objected to because of the following informalities:

Page 2, line 15, 'autinducer' should be 'autoinducer',

Page 3, line 23, 'individual in an individual' should be 'individual is an individual',

Page 7, line 18, 'autinducer' should be 'autoinducer',

Page 10, line 15, 'regima' should be 'regimens',

Page 11, line 7, 'polyetheylene' should be 'polyethylene',

Page 17. line 32, 'was was' should be 'was',

Appropriate correction is required.

Priority Statement

10. The status of all priority documents should be updated.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 44, 45, and 54-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44, 45, and 54-76 recite a method of selecting inhibitors/syngerists of "an" and "the" autoinducer molecule of *P. aeruginosa*. It is unclear from the claim

language how many autoinducers are being claimed. It is recommended that the language be consistent throughout the claims.

Claims 65-70 depend from claim 54. Claim 54 is the method of claim 44, "wherein the autoinducer molecule comprises a molecule" of a particular formula. Claim 65 recites "The method of claim 54 wherein the molecule is purified from its native source." It is unclear to which molecule in claim 54 that claims 65-70 are referring, i.e., the autoinducer molecule or the molecule which the autoinducer comprises.

The use of "*E.* coli MG4" as the sole means of identifying the a bacteria which contains plasmid pKDT17 renders claims 74-76 indefinite because "*E.* coli MG4" is merely a laboratory designation which does not clearly define the product since different laboratories may use the same laboratory designation to define completely distinct strains of *E. coli* .

14. Claims 44, 45, 54-58, and 60-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of selecting inhibitors or syngergists of the specific autoinducer N-(3-oxododecanoyl)homoserine lactone of *P. aeruginosa*, does not reasonably provide enablement for methods of selecting inhibitors or syngergists of any/all other autoinducers of *P. aeruginosa*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches one autoinducer, autoinducer N-(3-oxododecanoyl)homoserine lactone of *P. aeruginosa*. The specification provides insufficient guidance and examples of any other autoinducer molecules or gene activity which is altered by substances other than N-(3-oxododecanoyl)homoserine lactone.

Thus, the claims merely constitute an invitation to experiment with first identifying any other autoinducers in *P. aeruginosa* and then to experiment with any gene expression which may correlate with the unknown autoinducers.

Conclusion

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

October 1, 2003